Comments on proposed PDAB regulations from James Gutman, member of Stakeholder Council

(COMMENTS ARE PERSONAL AND NOT REPRESENTATIVE OF ANY ORGANIZATION)

Thank you for the opportunity to comment on the PDAB's well-crafted proposed regulations, including ones related to the cost-review process and proprietary information. In general, I agree with the approach and with the thorough manner by which the PDAB under the regulations would make the critical decisions needed for the success of its important mission. The bulk of the suggestions below relate to ways to ensure that all relevant information is considered at the time needed to keep the process moving as quickly as feasible. This in turn would help decisions to be made as promptly as feasible and for needed and justified cost relief to occur in a timely manner.

Here are the specific comments, listed and identified in the order (with numbered sections) that they appear in the proposed regulations, all of which are from COMAR 14.01:

From 01.02: Each of the definitions are good, especially the comprehensive definition of insulins to include all NDCs in the class. This is important since the PDAB should keep all insulins in the category of spotlighted drugs to be investigated even though there is some relief on insulins stemming from the 2022 federal Inflation Reduction Act and manufacturers' recent voluntary moves to cut some insulin-drug prices. The federal law's insulin changes apply only to Medicare, the manufacturer program programs could change and are not comprehensive (they don't cover all insulin products), and there is no Maryland law in effect yet to cut insulin prices for unemployed persons not eligible for Medicare.

From 02.02: I commend the clear phrasing here that the entity claiming an exemption from the PDAB fee assessment bears completely the burden of demonstrating that it qualifies for the exemption.

From 02:03: The proposed regulations are correct in taking into account "the publicly available data" on direct-to-consumer advertising spending for the Rx drug product involved in a pricing review. This information should be considered as part of the original review process rather than at a later stage since such spending plays an important role in high prices for drugs. Similarly, the section requiring price data for purchases of the same drug outside the U.S., including prices charged for pharmacies and wholesalers, is fundamental and important and should be part of the initial analysis, as PDAB member Gerard Anderson said in the April PDAB meeting, rather than just if the PDAB can't decide on the affordability of the drug in other ways. I agree with PDAB member Joseph Levy's suggestion that the international data should be limited to just certain highly industrialized countries so that comparisons are meaningful. And I agree with PDAB-member points that any federal financial support for research and development of the drug should be considered in the initial analysis for similar reasons.

I agree totally with the provisions requesting specific information on price concessions, discounts and rebates from other important entities in the Rx drug purchase process, including insurers, distributors and PBMs. The requests for them to furnish information on price concessions, discounts, and rebates, as well as "therapeutic alternatives," formulary placement, benefit designs and (for PBMs) gross and net revenues in the most recent year are both appropriate and necessary.

Similarly, the provisions that would allow cost reviews to include therapeutic alternatives, patient access, comparative effectiveness analysis, patient cost share, prevalence and seriousness of the disease treated, number of manufacturers of the drug (for generic drugs), gross state spending, and number of Maryland patients on the drug are excellent and necessary. The same section, though, goes on to include the change in total spending and utilization for the drug in the state in the "two most recent available calendar years." It will be very important for the PDAB to get data on just-completed years since earlier data may not furnish the needed information on recent price hikes and their impact. Similarly, the board needs to be able to get recent information on profit margins and measures of cost effectiveness for drugs under consideration for actions. I suggest the PDAB put additional phrasing in the regulations to help ensure that.

Near the end of this section, the proposed rules mention that the PDAB's rules should include "cost of access by priority populations and impact on equity." These are very important, as is the mention of "therapeutic benefit" of the product, patent-management strategies related to the drug's life cycle, and "market exclusivities." I commend the proposed rules' consideration of these items.

It is important that Rx entities respond in a timely manner to PDAB requests for information on any of these and related subjects. With this in mind, I agree with PDAB member Gerard Anderson that the time limit for responses should be 30 days rather than the 60 days contemplated in the proposed regulations.

The provisions relating to minimizing response times and reaching needed decisions quickly also relate to the anticipated claims by regulated entities that the material requested is confidential, trade secret or proprietary. As I mentioned in the April 24 Stakeholder Council meeting, there should be clear provisions in the regulations about what would be done about such claims that the PDAB finds to be false as well as about what to do when regulated entities do not comply with the board's requests for needed information within reasonable time periods. This should be added to the proposed regulations.

From 01.04: I applaud the provision here that would empower the board to seek additional information from the submitter and the original creator (if that can be determined) needed to determine whether anything claimed by the regulated entities to be confidential, trade-secret and/or proprietary information really belongs in this category. If it does, the protections — including closed sessions —proposed by the board to consider such matters are clearly appropriate. But it is important for the board to have the authority in the regulations to ensure that such protection is not abused.